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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,228	10/12/2001	Lothar W. Kleiner	ARC 2427 N1	9517

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EXAMINER	
STITZEL, DAVID PAUL	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,228	KLEINER ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,10-20,22,28-61 and 64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,10-20,22,28-61 and 64* is/are rejected.

7)☒ Claim(s) *12,13,15,16,18,31,47 and 51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/12/01; 10/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

OFFICIAL ACTION

Rejoinder of All Previously Withdrawn Claims

Upon reconsideration of the restriction requirement that was made in the Official Action mailed on August 14, 2003, claims 14, 17-20, 22, 28-33, 40, 42-46, 48-52, 54, 55, 57, 58, 60 and 61, which were previously withdrawn from consideration as a result of the aforementioned restriction requirement, are hereby rejoined under 37 CFR 1.104. Since all of the claims that were previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the aforementioned restriction requirement made in the above referenced Official Action is hereby withdrawn. As a result, the rejoined claims will be examined herein on the merits for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all statutory criteria for patentability, including the requirements set forth in 35 U.S.C. §§ 101, 102, 103 and 112.

Status of Claims

Claims 2, 4-9, 21 and 23-27 were canceled by a preliminary amendment filed on May 13, 2002. In addition, claims 62 and 63 were canceled by an amendment, which was filed on November 17, 2003 in response to the Office Action that was mailed on August 14, 2003. As previously mentioned, claims 14, 17-20, 22, 28-33, 40, 42-46, 48-52, 54-55, 57-58 and 60-61 have been rejoined. As a result, claims 1, 3, 10-20, 22, 28-61 and 64 are currently pending and therefore examined herein on the merits for patentability.

Groups of Inventions

I. Claims 1, 3, 10, 13-16, 34, 35, 39-47, 53, 55, 56 and 59-61 are drawn to a rate controlling membrane.

II. Claims 17-20, 22, 28-31, 48-51, 54, 57 and 58 are drawn to a method of processing a rate controlling membrane.

III. Claims 11, 12, 32, 33, 36-38, 52 and 64 are drawn to a fluid-imbibing drug delivery device.

Claim Objections - 35 U.S.C. § 112, Fourth Paragraph

The following is a quotation of the fourth paragraph of 35 U.S.C. § 112, which forms the basis of the claim objections as set forth under this particular section of the Official Action:

> Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

In addition, the following is an in-part quotation of the relevant portion of 37 CFR 1.75(c), which also forms the basis of the claim objections as set forth under this particular section of the Official Action:

> One or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim.

35 U.S.C. § 112, fourth paragraph, and 37 CFR 1.75(c) both require that a claim in dependent form shall be construed to incorporate by reference all the limitations of the independent claim to which the dependent claim refers and that the dependent claim shall further limit the subject matter claimed in the independent claim. See MPEP 2164.08.

Claims 12, 13, 15, 16, 18, 31, 47, and 51 are objected to under 35 U.S.C. § 112, fourth paragraph, and 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of the independent claim to which the dependent claims refers. Applicant is required to cancel the dependent claims; amend the dependent claims so as to place the claims in proper dependent form; or rewrite the dependent claims in independent form.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejections as set forth under this particular section of the Official Action:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46, 49 and 54 are rejected under 35 U.S.C. § 112, first paragraph, as containing new matter and failing to comply with the written description requirement. The aforementioned claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More specifically, there is no support in the specification for the moisture content range of about 1% to 2%, which is recited within claim 46. The specification only provides support for a moisture content range of 0% to 1% (Fig. 14; Fig. 15; Fig. 16; and Example 11). As a result, claim 46 is therefore rejected under 35 U.S.C. § 112, first paragraph, as containing new matter and for failing to comply with the written description requirement. In addition, there is no support in the specification for the cooling time period of about 0.1 hour – 250 hours, which is recited within claims 49 and 54. The specification only provides support for a cooling time period of about 0.1 hour – 150 hours (pages 8 and 9, paragraph 0045). As a result, claims 49 and 54 are therefore rejected under 35 U.S.C. § 112, first paragraph, as containing new matter and for failing to comply with the written description requirement.

Claim Rejections - Nonstatutory Double Patenting

A nonstatutory double patenting rejection of the "obviousness-type" is based on a judicially created doctrine grounded in public policy (a policy reflected in 35 U.S.C. § 101) so as to prevent not only the unjustified or improper timewise extension of the "right to exclude" granted by a patent, but also possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); and *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned or assigned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. See MPEP § 804. However, this does not mean that one is absolutely precluded from all use of the patent disclosure. See MPEP § 804. For example, the specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Furthermore, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-442, 164 USPQ 619, 622

(CCPA 1970). The court in *Vogel* stated that one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court in *Vogel* also pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. § 103, since only the disclosure of the invention claimed in the patent may be examined."

1. Claims 1, 3, 10, 13-16, 34, 35, 39-47, 53, 55, 56 and 59-61, which are drawn to the invention in Group I, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 10 and 13-16 of U.S. Patent Number 6,375,978, which issued to the common inventive entity of Kleiner et al. on April 23, 2002, and is also commonly assigned to ALZA Corporation. The following chart sets forth not only the claim limitations in the instant application, but also the conflicting claims and those corresponding portions of the specification within the patent disclosure that provide support for the conflicting claims, which are present within U.S. Patent Number 6,375,978.

Rate Controlling Membrane

Patent Application Serial Number 09/641,217; Tsuchida et al.; Filed 8/18/00		U.S. Patent No. 6,375,978			
Claim	**Limitation**	**Claims**	**Col.**	**Lines**	**Fig.**
1	rate controlling membrane implantable drug delivery device elevated annealing temperature is about 5C - 30C below Tm of membrane annealed for a period of about 1 hour - 250 hours subsequently incorporated into the drug delivery device	1	2 3 8	56-67 1-3 3-13	
3	rate controlling membrane polyurethane or polyether blocked amide copolymer	1 2 10	3 8 9	35-42 59-67 1-10	
10	rate controlling membrane polyurethane	1 2 10	3 8 9	35-42 59-67 1-10	

13	rate controlling membrane elevated annealing temperature is about 45C - 80C annealed for a period of about 1 hour – 75 hours	1 13	5	24-30	
14	rate controlling membrane elevated annealing temperature is about 5C - 30C below Tm of membrane annealed for a period of about 1 hour - 250 hours cooled to ambient conditions prior to incorporation	1 14	3 4 5	29-34 3-4 9-14	
15	rate controlling membrane elevated annealing temperature is about 52C - 72C annealed for a period of about 2 hours – 36 hours	1 15	5	51-55	
16	rate controlling membrane elevated annealing temperature is about 55C - 75C annealed for a period of about 12 hours – 48 hours	1 16	9	27-31	
34	rate controlling membrane polyether blocked amide copolymer	1 2 10	3 8 9	35-42 59-67 1-10	
35	rate controlling membrane single aliphatic polyether polyurethane, or blend of aliphatic polyether polyurethanes	1 2 10	3 8 9	35-42 59-67 1-10	
39	rate controlling membrane relaxed at room temperature for about 12 hours - 168 hours before annealing	1	5 9	30-33 31-39	
40	rate controlling membrane relaxed at room temperature for about 12 hours - 168 hours before annealing elevated annealing temperature is about 5C - 30C below Tm of membrane annealed for a period of about 1 hour - 250 hours subsequently incorporated into the drug delivery device	1	3 5 9	29-34 24-33 31-39	
41	rate controlling membrane elevated annealing temperature is about 52C - 72C annealed for a period of about 2 hours – 36 hours subsequently incorporated into the drug delivery device	1 15	3 5	29-34 51-55	
42	rate controlling membrane elevated annealing temperature is about 52C - 72C annealed for a period of about 2 hours – 36 hours cooled to ambient conditions prior to incorporation	1 14 15	3 4 5	29-34 3-4 9-14, 51-55	
43	rate controlling membrane relaxed at room temperature for about 12 hours - 168 hours before annealing elevated annealing temperature is about 52C - 72C annealed for a period of about 2 hours – 36 hours subsequently incorporated into the drug delivery device	1 15	3 5 9	29-34 30-33, 51-55 31-39	
44	rate controlling membrane dried to about 0% - 1% moisture content before annealing maintaining said moisture content during annealing elevated annealing temperature is about 52C - 72C annealed for a period of about 2 hours – 36 hours subsequently incorporated into the drug delivery device	1 15	3 4 5 6 17	29-34 62-64 51-55 12-18 5-18	14 15 16

45	rate controlling membrane	1	3	29-34	
	relaxed at room temperature for about 12 hours - 168 hours before annealing	14	4	3-4	
	elevated annealing temperature is about 52C - 72C	15	5	9-14,30-33,51-55	
	annealed for a period of about 2 hours – 36 hours		9	31-39	
	cooled to ambient conditions prior to incorporation				
46	rate controlling membrane	1	3	29-34	14
	relaxed at room temperature for about 12 hours - 168 hours	14	4	3-4, 62-64	15
	dried to about 1% - 2% moisture content before annealing	15	5	9-14,30-33,51-55	16
	maintaining said moisture content during annealing		6	12-18	
	elevated annealing temperature is about 52C - 72C		9	31-39	
	annealed for a period of about 2 hours – 36 hours		17	5-18	
	cooled to ambient conditions prior to incorporation				
47	rate controlling membrane	1	9	27-31	
	elevated annealing temperature is about 50C - 80C				
	annealed for a period of about 4 hours – 72 hours				
53	rate controlling membrane	1	3	29-34	
	elevated annealing temperature is about 45C - 80C	13	5	24-30	
	annealed for a period of about 1 hour – 75 hours				
	subsequently incorporated into the drug delivery device				
55	rate controlling membrane	1	2	56-67	
	exhibiting decreased water uptake variability		3	1-3	
			9	34-39	
56	rate controlling membrane	1	3	35-42	
	polyurethane or polyether blocked amide copolymer	2	8	59-67	
	elevated annealing temperature is about 55C - 75C	10	9	1-10, 27-31	
	annealed for a period of about 12 hours – 48 hours	16			
59	rate controlling membrane	1	3	35-42	
	polyether blocked amide copolymer	2	8	59-67	
		10	9	1-10	
60	annealed rate controlling membrane	1	2	56-67	
	exhibiting decreased variability in both water uptake and water permeability		3	1-3	
			9	34-39	
61	annealed rate controlling membrane	1	2	56-67	
	exhibiting decreased water uptake variability over time		3	1-3	
			9	34-39	

2. Claims 17-20, 22, 28-31, 48-51, 54, 57 and 58, which are drawn to the invention in Group II, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-20, 22, 28-31 of U.S. Patent Number 6,375,978, which issued to the common inventive entity of Kleiner et al. on April 23, 2002, and is also commonly assigned to ALZA Corporation. The following chart sets forth not only the claim limitations in the instant application, but also the conflicting claims and those corresponding portions of the specification within the patent disclosure that provide support for the conflicting claims, which are present within U.S. Patent Number 6,375,978.

Method of Processing a Rate Controlling Membrane

Patent Application Serial Number 09/641,217; Tsuchida et al.; Filed 8/18/00		U.S. Patent No. 6,375,978			
Claim	Limitation	Claims	Col.	Lines	Fig.
17	method of processing a rate controlling membrane	17	2	56-67	
	for use in an implantable drug delivery device	28	3	1-3, 29-34	
	relaxed at room temperature for about 12 hours - 168 hours before annealing	29	5	24-33	
	elevated annealing temperature is about 5C - 30C below Tm of membrane		8	3-13	
	annealed for a period of about 1 hour - 250 hours		9	31-39	
	subsequently incorporated into the drug delivery device				
18	method of processing a rate controlling membrane	17	5	24-30	
	elevated annealing temperature is about 45C - 80C	18			
19	method of processing a rate controlling membrane	17	5	24-30	
	elevated annealing temperature is about 45C - 80C	18			
	annealed for a period of about 1 hour - 75 hours	19			
20	method of processing a rate controlling membrane	17	4	3-4	
	elevated annealing temperature is about 45C - 80C	18	5	9-14, 24-30	
	annealed for a period of about 1 hour - 75 hours	19			
	cooled to ambient conditions for about 0.1 hour - 150 hours	20			
	subsequently incorporated into the drug delivery device				
22	method of processing a rate controlling membrane	17	3	35-42	
	polyurethane or polyether blocked amide copolymer	22	8	59-67	
		30	9	1-10	
28	method of processing a rate controlling membrane	17	5	30-33	
	relaxed at room temperature for at least about 12 hours before annealing	28	9	31-39	
29	method of processing a rate controlling membrane	17	5	30-33	
	relaxed at room temperature for at least about 48 hours before annealing	29	9	31-39	

30	method of processing a rate controlling membrane polyurethane	17 22 30	3 8 9	35-42 59-67 1-10	
31	method of processing a rate controlling membrane elevated annealing temperature is about 55C - 75C annealed for a period of about 12 hours - 48 hours	17 31	9	27-31	
48	method of processing a rate controlling membrane relaxed at room temperature for about 12 hours - 168 hours before annealing elevated annealing temperature is about 5C - 30C below Tm of membrane annealed for a period of about 1 hour - 250 hours subsequently incorporated into the drug delivery device	17 28	3 5 9	29-34 24-33 31-39	
49	method of processing a rate controlling membrane relaxed at room temperature for about 12 hours - 168 hours before annealing elevated annealing temperature is about 5C - 30C below Tm of membrane annealed for a period of about 1 hour - 250 hours cooled to ambient conditions for about 0.1 hour - 250 hours subsequently incorporated into the drug delivery device	17 20 28	3 5 9	29-34 9-14, 24-33 31-39	
50	method of processing a rate controlling membrane polyether blocked amide copolymer	17 22	3 8 9	35-42 59-67 1-10	
51	method of processing a rate controlling membrane polyether blocked amide copolymer elevated annealing temperature is about 55C - 75C annealed for a period of about 12 hours - 48 hours	17 22 31	3 8 9	35-42 59-67 1-10, 27-31	
54	method of processing a rate controlling membrane relaxed at room temperature for about 12 hours - 168 hours dried to about 0% - 1% moisture content before annealing maintaining said moisture content during annealing elevated annealing temperature is about 5C - 30C below Tm of membrane annealed for a period of about 1 hour - 250 hours cooled to ambient conditions for about 0.1 hour - 250 hours subsequently incorporated into the drug delivery device	17 20 28	3 4 5 6 9 17	29-34 3-4, 62-64 9-14, 24-33 12-18 31-39 5-18	14 15 16
57	method of processing a rate controlling membrane relaxed at room temperature for about 12 hours - 168 hours before annealing elevated annealing temperature is about 45C - 80C annealed for a period of about 1 hour - 250 hours subsequently incorporated into the drug delivery device	17 18 28	5 9	24-33 31-39	
58	method of processing a rate controlling membrane relaxed at room temperature for about 12 hours - 168 hours before annealing elevated annealing temperature is about 45C - 80C annealed for a period of about 1 hour - 75 hours subsequently incorporated into the drug delivery device	17 18 19 28	5 9	24-33 31-39	

3. Claims 11, 12, 32, 33, 36-38, 52 and 64, which are drawn to the invention in Group III, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 32, 33 and 35 of U.S. Patent Number 6,375,978, which issued to the common inventive entity of Kleiner et al. on April 23, 2002, and is also commonly assigned to ALZA Corporation. The following chart sets forth not only the claim limitations in the instant application, but also the conflicting claims and those corresponding portions of the specification within the patent disclosure that provide support for the conflicting claims, which are present within U.S. Patent Number 6,375,978.

Fluid-Imbibing Drug Delivery Device

Patent Application Serial Number 09/641,217; Tsuchida et al.; Filed 8/18/00		U.S. Patent No. 6,375,978			
Claim	**Limitation**	**Claims**	**Col.**	**Lines**	**Fig.**
11	fluid-imbibing drug delivery device annealed rate controlling membrane positioned in a sealing relationship with an internal surface of one end of an impermeable reservoir impermeable reservoir contains a piston piston divides the impermeable reservoir into a drug-containing chamber and a water-swellable agent containing chamber water-swellable agent containing chamber is provided with an outlet which accommodates the rate controlling membrane	11 32 35	2 3 8	56-67 1-3 37-42	4
12	fluid-imbibing drug delivery device drug-containing chamber	11 32 35	8	37-42	4
32	fluid-imbibing drug delivery device annealed rate controlling membrane positioned in a sealing relationship with an internal surface of one end of an impermeable reservoir impermeable reservoir contains a piston piston divides the impermeable reservoir into a drug-containing chamber and a water-swellable agent containing chamber water-swellable agent containing chamber is provided with an outlet which accommodates the rate controlling membrane	11 32 35	2 3 8	56-67 1-3 37-42	4
33	fluid-imbibing drug delivery device annealed rate controlling membrane is plug-shaped	11 32 33 35	8	53-54	4

36	fluid-imbibing drug delivery device annealed rate controlling membrane drug-containing chamber containing an opioid analgesic drug	11 35	8 9 10	37-42 46-49 14	4
37	fluid-imbibing drug delivery device annealed rate controlling membrane drug-containing chamber containing an antiviral drug	11 35	8 9	37-42 46-49, 63-64	4
38	fluid-imbibing drug delivery device annealed rate controlling membrane drug-containing chamber containing an antineoplastic drug	11 35	8 9	37-42 46-49, 61	4
52	fluid-imbibing drug delivery device annealed rate controlling membrane positioned in a sealing relationship with an internal surface of one end of an impermeable reservoir impermeable reservoir contains a piston piston divides the impermeable reservoir into a drug-containing chamber and a water-swellable agent containing chamber water-swellable agent containing chamber is provided with an outlet which accommodates the rate controlling membrane	11 32 35	2 3 8	56-67 1-3 37-42	4
64	fluid-imbibing drug delivery device annealed rate controlling membrane drug-containing chamber containing leuprolide	11 35	8 9 10	37-58 46-49 15-16	4

Remarks

The following is a list of prior art patents made of record and considered pertinent to the applicant's disclosure, but are not however currently relied upon in construing the claim rejections as set forth herein:

U.S. Patent Number 5,728,396, which issued to Perry et al. on March 17, 1998;
U.S. Patent Number 5,024,842, which issued to Edgren et al. on June 18, 1991; and
U.S. Patent Number 4,931,285, which issued to Edgren et al. on June 5, 1990.

Conclusion

In conclusion, claims 1, 3, 10, 13-16, 34, 35, 39-47, 53, 55, 56 and 59-61, which are drawn to the invention in Group I, are rejected under obviousness-type double patenting as being unpatentable over claims 1, 2, 10 and 13-16 of U.S. Patent Number 6,375,978. In addition, claims 17-20, 22, 28-31, 48-51, 54, 57 and 58, which are drawn to the invention in Group II, are rejected under obviousness-type double patenting as being unpatentable over claims 17-20, 22, 28-31 of U.S. Patent Number 6,375,978. Furthermore, claims 11, 12, 32,

33, 36-38, 52 and 64, which are drawn to the invention in Group III, are rejected under obviousness-type double patenting as being unpatentable over claims 11, 32, 33 and 35 of U.S. Patent Number 6,375,978.

In summary, claims 1, 3, 10-20, 22, 28-61 and 64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 10, 11, 13-20, 22, 28-33 and 35 of U.S. Patent Number 6,375,978, which issued to the common inventive entity of Kleiner et al. on April 23, 2002, and is also commonly assigned to ALZA Corporation.

As previously discussed, the subject matter claimed in the instant application is fully taught in the conflicting claims and those corresponding portions of the specification within the patent disclosure of the Kleiner et al. '978 patent that provide support for the conflicting claims, which is obvious in light of the fact that both the instant application and the conflicting Kleiner et al. '978 patent are claiming common subject matter.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The examiner can normally be reached on Monday-Friday, from 8:30AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached at 571-272-0887. The fax number for Group Art Unit 1616, which is where this application or proceeding is assigned, is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DPS

Gary L. Kunz

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